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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,211	01/02/2004	Raymond J. H. Westheim	SYN-0040	6650

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EXAMINER	
SACKEY, EBENEZER O	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,211	WESTHEIM ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) *22-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-33 are pending.

Note this application ahs been transferred from Dr. Laura Stockton to the present Examiner.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 08/18/04 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the term "comprising" in compound claim is inappropriate because the term is inclusive and fails to exclude unrecited elements. Comprising leaves the claim open for inclusion of unspecified elements. *Ex parte Davis et al.*,80 USPQ 448 (PTO Bd. App. 1948) and *Gottzein et al.*,168 USPQ.

Claim 5 has been defined entirely by reference to the x-ray diffraction in the specification (Figure 6). Claims must, under modern practice, stand alone to define an invention, and incorporation into claims by express reference to the specification is not permitted. *Ex parte Fressola,* 27 U.S.P.Q. .2d 1608, (1993). Additionally, the use of the term "residue" in the claims render the claims indefinite because there is no information as to which portion of the molecule remains.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Coates et al., (U.S.Patent number 4,695,578).

Applicants claim a solid crystalline ondansetron compound in which the melting endotherm peak is greater than or equal to 240^0C with a water content of 1.3 to 1.5-wt%.

Coates et al., discloses ondansetron crystal compounds. See Preparation 6, Example 3a, 8. It is noted that Coates et al., is silent on the water content and the melting endotherm peak of the disclosed ondansetron compound. However, it is assumed that since the reference compound is the same as the claimed compound structurally and chemically it will of necessity poses the claimed water content and the endotherm peak.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al., (U.S.Patent number 4,695,578)('578').

Applicants claim a solid crytalline ondansetron compound that discloses a melting endotherm peak greater than or equal to 240^{0}C with a water content of 1.3 to 1.5-wt%.

Coates et al., discloses ondansetron crystal compounds, which are similar to the instantly claimed ondansetron compounds. See the entire reference especially column 15, Example 3a. It is noted that the reference is silent on the water content of the compounds, the melting endotherm peak, particle size of the compound prepared etc. These limitations are present in the reference compounds since the reference compounds are structurally and chemically the same as the claimed compounds. Thus, the instant claims differ from '578' in the particle size of the compound (claims 15 and 16). These differences are not considered patentable distinction and are thus, *prima facie* obvious absent a showing of unexpected properties. There is no indication by way of evidence or otherwise in the specification that discloses the significance of the claimed particles from the reference compounds.

The claimed particle sizes are an obvious modification well within the purview of the skilled artisan in the art. The claimed sizes are merely optimization of variables, which are not patentable absent unexpected result due to these variables, which are a difference in kind, and not merely in degree from that of the prior art. *In re Aller,* 105 USPQ 233, (1955). Also see *In re Boesch*, 205 USPQ, 215, (1980).

Therefore, at the time of filing this application, one of ordinary skill in the art would thus, have been motivated to prepare ondansetron compounds as disclosed by Coates et al., with the expectation that the resulting product (compound) would maintain high yield and/or selectivity because precise indicated particle sizes are preferred.

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare ondansetron compounds as disclosed by the reference with particle sizes elements because explicit particle sizes are preferred and maintaining those sizes have been expected to operate with a reasonable expectation of success. Hence, the instantly claimed compounds would therefore have been suggested to one of ordinary skill in the art absent a showing of unexpected properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS
September 29, 2006

James O.Wilson
Supervisory Patent Examiner
Art Unit 1624, Group 1600
Technology Center 1